



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 121

[Docket No. FDA-2013-N-1563]

Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm;
Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a document that appeared in the Federal Register of December 24, 2013 (78 FR 78064), entitled "Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (draft RA Appendix) to June 30, 2014. We are taking this action to keep the comment period for the draft RA Appendix consistent with the comment period for the proposed rule.

DATES: FDA is extending the comment period on the draft RA Appendix. Submit either electronic or written comments on the proposed rule and the information collection by June 30, 2014.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2428.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 24, 2013, we published a document entitled "Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA Appendix) with a 100-day comment period on the provisions of the proposed rule.

FDA has received requests for an extension of the comment period on the proposed rule entitled "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" (78 FR 78014). This document directly relates to the proposal. The requests conveyed concern that the current 100-day comment period does not allow time to thoroughly analyze the proposal, due to the inherent complexity and unique nature of food defense issues. FDA has considered the requests and is granting an extension of the comment period to June 30, 2014, for the draft RA Appendix to allow interested persons additional time to submit comments. Elsewhere in this issue of the Federal Register, we are also extending the comment period for the proposed rule "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration." To clarify, FDA is requesting comment on all issues raised by the document.

II. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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